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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,449	02/05/2002	Gunter Muller	DEAV2001/0002	7390

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,449	MULLER ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2-5-02

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending in the instant application and are subject to the following restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to yeast strains which can no longer grow on substrates with hexoses as the sole carbon source and whose ability of growing on a hexose substrate can be restored when a GLUT4 gene is expressed in the strain, and methods of making such strains, classified in class 435, subclasses 252.3 & 471.

II. Claim 11, drawn to a method of identifying a compound that increases or reduces the amount of hexose transported by means of a Glut4 protein, classified in class 435, subclass 6.

III. Claims 12-13, drawn to pharmaceutical compositions comprising a compound that modulates the amount of hexose transported by means of a Glut4 compound and methods of using such compositions to treat diabetes or adiposity, classified in class 514, subclass 1.

IV. Claims 14-15, drawn to methods of screening for a compound that modulates the amount of hexose transported by means of a Glut1 protein, classified in class 435, subclass 6.

V. Claims 16-17, drawn to pharmaceutical compositions comprising a compound that modulates the amount of hexose transported by means of a Glut1 compound

and methods of using such compositions to treat diabetes or adiposity, classified in class 514, subclass 1.

VI. Claims 18-19, drawn to strains of *S. cerevisiae* which can no longer grow on substrates with hexoses as the sole carbon source and whose ability to grow on hexoses as the sole carbon source is restored with a Glut1 gene is expressed in the strain, and methods of making such strains, classified in class 435, subclass 252.3 & 471.

VII. Claim 20-21 & 23-24, drawn to nucleic acids encoding Glut1 proteins, classified in class 536, subclass 23.1.

VIII. Claims 22 & 25, drawn to Glut1 polypeptides, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I & II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the yeast strains of Group I can be used to express other heterologous proteins.

Invention of Group I-II and Groups III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions, the invention of Groups I-II and Groups III-VIII are not disclosed as usable together. Moreover, the Glut4 strains of Groups I-II are operationally distinct from the Glut1 yeast strains, pharmaceutical compositions, methods of treatment, nucleic acids encoding Glut1 proteins and Glut1 proteins of the methods/compositions of the other groups and have different effects. For example, the compounds identified by the methods of Group II can be produced and identified by other methods prior to their use in the methods of Group III. Thus, the inventions of Group I-II are capable of supporting separate patents from those supported by the inventions of Groups III-VIII.

Inventions of Group III and Groups IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation and different effects. For example, there is no evidence of record that compounds identified as modulating the functions of Glut 4 function (e.g. Group III) would be identified or useful in the inventions dependent upon Glut1 function (e.g. Groups IV-V). Therefore, the invention of Group III is different and distinct from those of Groups IV-VIII.

The inventions of Group IV and Group V are related as a process of identifying a compound having a useful property (Group IV) and the product identified as well as a method of using the product (Group V). The products of Group V can be produced and identified by other methods (e.g. in vitro methods using purified Glut1 protein and synthetically produced small molecule compounds). The methods of Groups IV & V comprise methods steps not present in or required for the other methods: providing a yeast strain complemented for growth on hexoses as

the sole carbon source due to the expression of functional Glut1 (Group IV) and administration of a pharmaceutical compound to a subject in need thereof (Group V). The end result of the different methods is different: identification of a functional compound (Group IV) and treatment of diabetes or adiposity in a subject (Group V).

Inventions of Groups VI-VII and Group IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Group VII can be used in alternative methods (e.g. production of the Glut1 protein for purification). The yeast strains of Group VI can be used to produce other heterologous proteins.

Inventions of Group IV and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as usable together and have different modes of operation, functions and effects. For example, the isolated proteins of Group VIII are not used in the methods of Group IV. Alternatively, the methods of Group IV are not required for the production of the protein of Group VIII.

Inventions of Group V and Groups VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different

modes of operation and different effects. The compositions of Group V are not used in the methods of the other groups and are not required for the use or production of the products of the other groups. The methods of Group V comprise methods steps not required for or present in the methods of the other groups (e.g. administration of a pharmaceutical composition to a subject) and have a different end result (e.g. treatment of a subject vs. generation of a yeast strain).

Inventions of Group VII and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Group VII can be labeled and used as probes to identify nucleic acids encoding similar proteins to that encoded by the nucleic acids of Group VII.

Inventions of Group VI and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different functions, effects and modes of operation. The yeast strains and methods of Group VI are not required for the production of the protein of Group VIII (which can be produced in other yeast strains and/or isolated from wildtype proteins). The isolated proteins of Group VIII are not required for or present in the methods of Group VI.

Inventions of Group VII and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, functions and effects. For example, the nucleic acids of Group VII are not required fro the production of the proteins of Group VIII (which can be made synthetically or isolated from wildtype yeast cells). The production and use of the nucleic acids of Group VII does not require the protein of Group VIII. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further, for those groups having the same classification, the nonpatent literature search required for each of these groups is different and distinct due to the different structural/functional characteristics of the nucleic acids and proteins in the different Glut1- and Glut4-dependent groups.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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